



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,763	12/22/2000	Kenneth Jacobs	GIN-6046CP	7028

5514 7590 08/01/2005

FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
----------	--------------

1656

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/745,763

Applicant(s)

JACOBS ET AL.

Examiner

Chih-Min Kam

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 265-267 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 265-267 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/27/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

S.O.U

Art Unit: 1656

DETAILED ACTION

1. The Request for Continued Examination (RCE) filed May 23, 2005 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

Status of Claims

2. Claims 265-267 are pending.

Applicants' amendment filed May 23, 2005 is acknowledged. Applicants' response has been fully considered. Claims 265 and 266 have been amended. Therefore, claims 265-267 are examined.

Oath/Declaration

3. Regarding defective oath, applicant has filed a supplemental application data sheet (ADS) on May 23, 2005 to provide information on the mailing address of inventor Vikki Spaulding. However, the ADS only lists city of residence, but no mailing address indicated. Please provide a supplemental ADS with the mailing address of Vikki Spaulding. Regarding correcting a typographical error in the spelling of inventor's name (Maurice Treacy), applicant's response is persuasive, and the objection is withdrawn.

Withdrawn Claim Rejections - 35 USC § 112

4. The previous rejection of claims 265 and 266 under 35 U.S.C. 112, first paragraph, for lack of written description on fragments of the amino acid sequence of SEQ ID NO:36; a polynucleotide encoding a protein comprising a fragment of SEQ ID NO:36, variant or homolog of the polynucleotide, is withdrawn in view of applicants' deletion of claim 265 parts (j), (k), (l), and claim 266, part (c), and applicant's response at page 6 in the amendment filed May 23, 2005.

Art Unit: 1656

5. The previous rejection of claim 265 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claim in the amendment filed May 23, 2005.

Maintained Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 265-267 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. The claims are directed to a polynucleotide comprising SEQ ID NO:35, specific fragments of SEQ ID NO:35, a nucleotide sequence of a protein coding sequence of clone bu45_2 deposited under accession number ATCC 98369, a polynucleotide encoding a protein comprising SEQ ID NO:36, or a polynucleotide capable of hybridizing under stringent conditions to the claimed polynucleotide (claim 265); a polypeptide comprising SEQ ID NO:36 or a specific fragment of SEQ ID NO:36 (residues 1-175), the amino acid sequence encoded by the cDNA insert of clone bu45_2 deposited under accession number ATCC 98369 (claim 266); and a gene corresponding to the cDNA sequence of SEQ ID NO:35 (claim 267). The specification indicates that the invention is related to the novel polynucleotides and the proteins encoded by such polynucleotides (page 5, lines 5-7), and a polynucleotide has been identified as clone "bu45_2", which encodes a secreted or transmembrane protein, and the nucleotide sequence of bu45_2 is determined as SEQ ID NO:35 (page 113, lines 2-15). The specification also indicates the nucleotide sequence of bu45_2 was searched against nucleotide sequence databases, which demonstrated at least some similarity with sequences identified as AA041196, AA452391, Q61260, R13864 and R18560; the predicted amino acid sequence for bu45_2 was searched

Art Unit: 1656

against amino acid databases, which demonstrated at least some similarity to sequences identified as R99416 (aminopeptidase precursor of *Aeromonas caviae*); and based on sequence similarity, bu45_2 proteins and each similar peptide may share at least some activity (page 113, lines 18-32). However, the specification does not disclose the sequence similarity between the identified polynucleotide sequences and SEQ ID NO:35, nor indicates the sequence similarity between the identified polypeptide sequences and bu45_2 proteins. Furthermore, the specification has not identified the activity of bu45_2 protein or peptide. Although the specification indicates the polypeptides and the proteins of the invention such as SEQ ID NO:35 and SEQ ID NO:36 are expected to exhibit one or more uses or biological activities, such as polynucleotides can be used for research by expressing recombinant proteins for analysis, characterization or therapeutic use; polypeptides and proteins can be used as nutritional sources or supplements; and proteins may exhibit cytokine, cell proliferation activity, immune stimulating or suppressing activity (pages 173-189), the direct correlation between the biological activity and the claimed polypeptide is not indicated, and the specific uses of the bu45_2 protein and polynucleotide are not demonstrated. For these reasons, the instant invention does not possess a specific and substantial utility or a well-established utility for the claimed polynucleotides and polypeptide, although there is a general utility that is applicable to the broad class of proteins or polynucleotides. The utility is not a substantial utility because it requires further research to identify or reasonably confirm a "real world" context of use. Basic research to characterize the claimed invention, use in an assay to identify modulators of the instant invention, production of antibodies to identify other related proteins or use of polynucleotides to identify other related sequences do not constitute substantial utilities.

Response to Arguments

Applicants indicate that bu45_2 is the same as the polypeptide identified as AAY58879 (See the attached Blast results). This polypeptide is described in WO 00/04157 as an N-acetylated alpha-linked acidic dipeptidase (NAALAD-ase). See NAALADIV in Fig. 6 of WO 00/04157 (pages 5-6 of the response).

The response has been considered, however, the argument is not found persuasive because WO 00/04157 is a post filing reference, and the specification fails to identify the polynucleotide of SEQ ID NO:35 and the peptide of SEQ ID NO:36 as the nucleotide and polypeptide sequences of N-acetylated alpha-linked acidic dipeptidase (NAALAD-ase) at the time of filing of the instant application. Moreover, the specification has not described the peptide of SEQ ID NO:36 exhibiting the enzymatic activity of NAALAD-ase, nor provides the guidance necessary for specific uses of the claimed polynucleotide and polypeptide. Failure to identify the biological activity of the claimed polypeptide and specific use of the claimed polynucleotide and polypeptide, the claimed invention does not meet the utility requirement of 35 U.S.C. § 101.

Maintained Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 265-267 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or

Art Unit: 1656

a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

New Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 265 is rejected under 35 U.S.C. 112; second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 265 is indefinite as to “hybridizing under stringent condition” in part (j), it is not clear what stringent condition is used for hybridization.

Maintained Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless-

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 265 and 266 remain rejected under 35 U.S.C. 102(a) as being anticipated by Jacobs *et al.* (WO 97/39030, October 23, 1997). The priority date for SEQ ID NOs:35 and 36 is March 19, 1998 (application 09/044,466).

Jacobs *et al.* teaches a protein comprising an amino acid sequence of SEQ ID NO:12 (472 amino acids), which has 99.7% sequence identity with SEQ ID NO:36 (see previously attached sequence match; claim 266, part (b)), and a polynucleotide sequence of AM282 full length

Art Unit: 1656

CDNA clone (SEQ ID NO:11; see attached nucleotide sequence match) contains nucleotides 57-623 of SEQ ID NO:35 (claim 265, part (d)).

Response to Arguments

In response, applicants indicate the disclosure in Jacobs upon which the § 102(a) rejection is founded is the work of the inventors of Claims 265 and 266. Applicants are considering filing an affidavit to this effect.

The response has been considered, however, the argument is not persuasive because applicant has not filed an affidavit to establish the reference is the work of the same inventive entity as the claimed invention (see MPEP § 2132.1). Thus, the rejection is maintained.

New Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless-

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 265 is rejected under 35 U.S.C. 102(b) as being anticipated by Meng *et al.* (U.S. Patent 5,470,719).

Meng *et al.* teaches two nucleotide sequences of SEQ ID NO:16 (20 bases) and SEQ ID NO:17 were used as primers for PCR to amplify the NT-3opt3 gene (column 16, lines 40-46; claim 265, part (j)), where SEQ ID NO:16 has some sequence identity to nucleotides 1680-1698 of SEQ ID NO:35 (see attached sequence match), since the claim only cites a polynucleotide capable of hybridizing under stringent condition, where the hybridization condition is not

Art Unit: 1656

indicated, any nucleotide sequence hybridizing to part of SEQ ID NO:16 meets the criteria of claim 265, part (j).

Conclusion

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner



**CHIH-MIN KAM
PATENT EXAMINER**

CMK

July 21, 2005